MAR 3 1 2004

K040583
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CD HORIZON® Spinal System
Summary of Safety and Effectiveness
March 2004

I. **Company:** **Medtronic Sofamor Danek, Inc. USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name: CD HORIZON® Spinal System**

III. **Classification Name: Spinal Interlaminal Fixation and Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw Spinal System (per 21 CFR Section 888.3050, 888.3060 and/or 888.3070)**

IV. **Product Description**

The CD HORIZON® Spinal System consists of a variety of rods, hooks, screws, CROSSLINK® plates, staples, and other connecting components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The CD HORIZON® Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. If necessary, the CD HORIZON® Spinal System can be connected to the VERTEX™ Reconstruction System through a rod connector.

Certain implant components from other Medtronic Sofamor Danek spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers; GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS® bolts; and Medtronic Sofamor Danek Multi-Axial rods and screws.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE® rods and screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 4.5mm rods and associated components may be used posteriorly.

The purpose of this 510(k) submission is to include additional 6.35mm titanium components to the CD HORIZON® Spinal System.

V. **Indications**

The CD HORIZON® Spinal System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used in a percutaneous, non-cervical, posterior approach with the SEXTANT

instrumentation, the CD HORIZON® screws are intended for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, CD HORIZON® components such as ECLIPSE® components are intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® SPIRE Plate is posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. Refer to the VERTEX™ Reconstruction System Package Insert for a list of the VERTEX™ indications of use.

VI. Substantial Equivalence

Documentation was provided which demonstrated the CD HORIZON® Spinal System to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K040583
Trade/Device Name: Modification to CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertbral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, NKB, KWP, KWQ
Dated: March 4, 2004
Received: March 5, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K040583

March 2004

510(k) Number (if known): K040583

Device Name: CD HORIZON® Spinal System

Indications for Use:

The CD HORIZON® Spinal System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used in a percutaneous, non-cervical, posterior approach with the SEXTANT instrumentation, the CD HORIZON® screws are intended for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, CD HORIZON® components such as ECLIPSE® components are intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® SPIRE Plate is posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. Refer to the VERTEX™ Reconstruction System Package Insert for a list of the VERTEX™ indications of use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)